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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/465,667 12/17/99 CEDGARD

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000530 HM22/0720
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EXAMINER

AFREMOVA, V

ART UNIT	PAPER NUMBER
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1651

12

DATE MAILED:

07/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/465,667	Applicant(s) Cedgart
	Examiner Vera Afremova	Art Unit 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on May 21, 2001

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 11, 12, and 14-28 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 11, 12, and 14-28 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). _____

16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) Other: _____

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DETAILED ACTION

Claims 11, 12 and 14-28 as amended are pending and under examination. Claim 13 is canceled by applicant. {Paper No. 11 filed 5/21/2001}.

Information Disclosure Statement

The information disclosure statement filed 8/15/2000 partially fails to comply with the provisions of 37CFR 1.97, 1.98 and MPEP § 609 because copies of references AS, AT and AR are missing and/or no concise explanation of the relevance of the references AS, AT and AR was provided. The Form PTO-1449 filed 8/15/2000 has been placed in the application file, but the information referred to therein has not been considered as to the merits.

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Objections and Claim Rejections - 35 U.S.C. § 112

The objection and rejection of claims under 35 U.S.C. 112-1, have been withdrawn in view of applicant's corrections of Latin names and cancellation of the claim 13.

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Claim Rejections - 35 U.S.C. § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 11, 12 and 14-28 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,396,631 [A] taken with US 5,422,346 [B], US 5,531,989 [C], US 5,527,556 [D] and US 4,021, 545 [E] as explained in the prior office action and repeated herein.

The claims are directed to a method for producing tablets with live lactic bacteria by step of mixing live lactic bacteria with fructose oligosaccharide or inulin and step of pressing the mixture into tablet. Some claims are/are further drawn to the use of particular species of lactic bacteria in the mixture such as *Lactobacillus bulgaricus*, *Lactobacillus plantarum*, *Streptococcus thermophilus* or *Bifidobacterium animalis*. Some claims are further drawn to incorporation of additives into the mixture such as starch or calcium diphosphate.

US 4,396,631 teaches a method for method for producing tablets with live lactic bacteria by step of mixing live lactic bacteria with starch or other materials suitable for tablets and step of pressing the mixture into tablets or forming tablets. The cited patent discloses that lactic bacteria retain high viability (2×10^8 cfu) after formation of tablets and during storage of tablets (col. 4, example 1). The cited method is lacking the disclosure of fructose oligosaccharide or inulin in the mixture intended for forming tablets.

US 5,422,346 discloses fructose oligosaccharide or inulin in the method for producing tablets and it teaches that inulin is compressed into tablets without the need of additional tableting

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material such as starch, for example : col. 8, lines 41-44. The cited patent also teaches that inulin is a growth promoting substrate of lactic bacteria such as *Bifidobacterium sp* and that pathogenic bacteria can not utilize inulin unlike beneficial bacteria in the gut of animals (col. 18, lines 25-37).

US 5,531,989 teaches method for producing dry mixture in powder or agglomerate form comprising 40-60 % by weight of inulin and/or fructose oligosaccharide and 0.1-20% by weight of lactic bacteria of *Lactobacillus sp.* and /or *Bifidobacterium sp.* including *L. bulgaricus* and *L. plantarum* (col. 13, lines 38-50 and col. 4, lines 1-30).

US 5,527,556 teaches method for producing semi-solid inulin products with live lactic bacteria in a form of cream (col.14, example 13) or paste and it teaches that incorporation of inulin makes possible to stabilize water and the resulting composition has viscosity which allows to from tablets (col.15, line 35).

US 4,021, 545 teaches a method for producing tablets comprising inulin and other additives such as starch or calcium diphosphate (col.5, example 4).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to incorporate inulin of the secondary references into lactic bacteria and/or bifidobacteria containing tablets in the method of US 4,396,631 with a reasonable expectation of success in obtaining tablets with beneficial effects with regard to promoting growth of beneficial lactic or bifidobacteria and suppressing growth of pathogenic bacteria as suggested by US 5,422,346 and as taught by US 5,531,989. Or it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to substitute inulin of the

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secondary references for starch in the lactic bacteria and/or bifidobacteria containing tablets in the method of US 4,396,631 with a reasonable expectation of success in obtaining pressed or compresses tablets since the use of inulin allows for the exclusion of additional tableting binder such as starch, for example, as taught by US 5,422,346. In addition, the cited US 5,527,556 also teaches a superior viscosity of the inulin containing semi-solid mixture if intended for tableting. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Response to Arguments

Applicant's arguments filed 5/21/2001 have been fully considered but they are not found persuasive.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning (see response page 5, par. 2), it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

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Further, applicant appears to argue that the cited prior art teaches everything but the applicant's invention such as the use of oligosaccharide or inulin together with lactic bacteria in a method for pressing tablets with bifidobacteria (see response page 6, par. 1-2). However, the cited prior art teaches the use of bifidobacteria in a method for preparing/pressing tablets wherein bifidobacteria remain viable (US '631). And the cited prior art also teaches that use of inulin in tablets or the use of inulin in a method for making tablets (US '346 and US '545). Thus, the claimed concept of using both components together in tablets or method for making/pressing tablets is/was clearly prima facie obvious particularly in view that it is known to use both components such as inulin and lactic bacteria in a form of powder or agglomerates in a method of making therapeutic preparations with viable lactic bacteria intended for administration (US '989). And it is also known that incorporation of oligosaccharide or inulin in therapeutical formulations has some valuable benefits such as promoting growth of lactic bacteria after administration to animal or humans (US '346).

Applicant seems to argue that the cited art is lacking suggestion that oligosaccharide would ensure viability of bacteria during tablet formation (see response page 7, par. 1). However, it is unclear as argued why this fact is not obvious for one having ordinary skill in the art since the prior art clearly teaches methods of making formulations with active and viable lactic bacteria intended for administration as living lactic bacteria products in a form of powder or agglomerates or semi-solids and inulin is known as a tableting component and as well as lactic bacteria

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lactic bacteria with inulin in a tablet or combining lactic bacteria with inulin in a powder or agglomerate.

Applicant's representative is invited to call examiner to schedule interview as requested (see response page 9).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova,

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July 20, 2001.



SANDRA E. SAUCIER
PRIMARY EXAMINER